

## **REMARKS**

In response to a restriction requirement, Applicant elected claims 50-53 of Group XVI, with traverse, and also added new claims 80-91, all of which are now under examination. Applicants also amended claims 50-54 to better reflect the nature of the invention. The new claims all depend directly or indirectly from amended claim 50 (part of elected Group XVI).

### **Information Disclosure Statement**

The Information Disclosure statement filed on 4 December 2000 was noted by the Examiner as containing GenBank Accession Numbers without a date or authorship. Applicant has endeavored to rectify this matter and provides the necessary information in the accompanying papers.

However, Applicant notes that two additional information disclosure statements were filed in this case, for a total of three. The first Information Disclosure Statement was filed 4 December 2000, the second Disclosure Statement was filed 12 February 2001 (initialed by the Examiner and attached to the Office Action) and the other was filed 29 July 2002 (which included a copy of an International Search Report). The record contains no indication of any review of the latter references despite acknowledgement by the Patent Office of receipt of these materials.

### **Specification Informalities**

The title was objected to as not be sufficiently descriptive. In response, Applicants have amended the title to recite the Examiner's suggested wording.

The priority claim was objected to for use of the phrase "continuation-in-part" when referring to a provisional application. In response, Applicants have amended the specification to recite that the present application is a continuation-in-part of a utility application and also claims priority of the recited provisional application.

### **Rejection Based on 35 U.S.C. §112, Second Paragraph**

Claims 51, 53 and 82-90 were rejected under section 112, paragraph 2, as being indefinite.

Claims 51 and 53 were rejected as indefinite for being unclear as to where the recited steps should be incorporated into the methods of claims 50 and 52, respectively. Applicants respond that there does not appear to be any ambiguity. Claims 52 and 53 have been canceled. Claim 51 recites the determination of the presence or absence of "at least one ABC1 polymorphism."

Claims 82-84 and 88-90 were rejected as indefinite for lack of antecedent basis in using the phrase "said polymorphisms" in reference to claims 50 and 52. In response, Applicants urge that there is no ambiguity because claim 50 recites determination of at least one polymorphism. Claim 50 provides the antecedent basis in the last 3 lines of the claim "wherein the presence of said at least one ABC1 polymorphism is indicative of a risk for developing said disease or condition." Claim 52 provides the proper antecedent basis in the first line of step (b).

Claim 85 was rejected as indefinite for use of the terms "subject" and "set of subjects." In response, Applicants have canceled claim 85.

Claim 86 was rejected as indefinite for the phrase "at least one polymorphism that indicates the propensity for developing said disease." In response, Applicants have canceled claim 86.

#### **Rejection Based on 35 U.S.C. §112, First Paragraph**

Claims 50, 51 and 80-84 were rejected under section 112, first paragraph, for failure to meet the written description requirement. In response, these claims have been amended to recite the polymorphic sites provided in Figure 11, which are enabled within the application as filed.

Claims 50-53 and 80-91 were rejected under section 112, paragraph 1, as being overly broad in attempting to cover a method involving any polymorphism. In response, Applicants have cancelled claims 52, 53 and 85-91. Applicants have also amended claims 50 and 51 to recite the specific mutations of Figure 11.

#### **Rejection Based on 35 U.S.C. §102**

Claims 50, 52, 80-82 and 85-88 was rejected under section 102(b) as anticipated by Rust et al.

In response, Applicants have cancelled claims 52 and 85-88. Applicants have also amended claim 50, and claims dependent therefrom, to recite the polymorphisms shown in Figure 11. Because these mutations are not recited in Rust, Applicants believe that this reference is no longer application. Applicants further contend that this reference would also not render the claims obvious because the location of the recited polymorphisms would not be indicated by the disclosure of Rust et al.

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Claims 50-53 and 80-91 were rejected under section 102(b) as anticipated by Bodzioch et al, which teaches genetic analysis of ABC1 sequences from subjects with Tangier's disease, which led to the identification of several mutations.

In response, Applicants have canceled claims 52 and 85-88. Applicants have also amended claim 50, and claims dependent therefrom, to recite the polymorphisms shown in Figure 11. Because these mutations are not recited in Rust, Applicants believe that this reference is no longer application. Applicants further contend that this reference would also not render the claims obvious because the location of the recited polymorphisms would not be indicated by the disclosure of Rust et al.

No additional fee is believed due in filing this paper. If any fee is due, Applicant requests that the Commission charge such fee to Deposit Account No. 03-0678.

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Respectfully submitted,



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